

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 5178  
OFFERED BY MR. BALLENGER**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

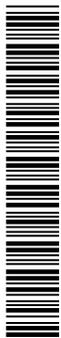
2 This Act may be cited as the “Needlestick Safety and  
3 Prevention Act.”

**4 SEC. 2. FINDINGS.**

5 The Congress finds the following:

6 (1) Numerous workers who are occupationally  
7 exposed to bloodborne pathogens have contracted  
8 fatal and other serious viruses and diseases, includ-  
9 ing the human immunodeficiency virus (HIV), hepa-  
10 titis B, and hepatitis C from exposure to blood and  
11 other potentially infectious materials in their work-  
12 place.

13 (2) In 1991 the Occupational Safety and  
14 Health Administration issued a standard regulating  
15 occupational exposure to bloodborne pathogens, in-  
16 cluding the human immunodeficiency virus, (HIV),  
17 the hepatitis B virus (HBV), and the hepatitis C  
18 virus (HCV).



1           (3) Compliance with the bloodborne pathogens  
2 standard has significantly reduced the risk that  
3 workers will contract a bloodborne disease in the  
4 course of their work.

5           (4) Nevertheless, occupational exposure to  
6 bloodborne pathogens from accidental sharps inju-  
7 ries in health care settings continues to be a serious  
8 problem. In March 2000, the Centers for Disease  
9 Control and Prevention estimated that more than  
10 380,000 percutaneous injuries from contaminated  
11 sharps occur annually among health care workers in  
12 United States hospital settings. Estimates for all  
13 health care settings are that 600,000 to 800,000  
14 needlestick and other percutaneous injuries occur  
15 among health care workers annually. Such injuries  
16 can involve needles or other sharps contaminated  
17 with bloodborne pathogens, such as HIV, HBV, or  
18 HCV.

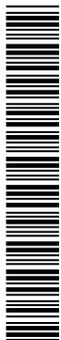
19           (5) Since publication of the bloodborne patho-  
20 gens standard in 1991 there has been a substantial  
21 increase in the number and assortment of effective  
22 engineering controls available to employers. There is  
23 now a large body of research and data concerning  
24 the effectiveness of newer engineering controls, in-  
25 cluding safer medical devices.



1           (6) 396 interested parties responded to a Re-  
2           quest for Information (in this section referred to as  
3           the “RFI”) conducted by the Occupational Safety  
4           and Health Administration in 1998 on engineering  
5           and work practice controls used to eliminate or mini-  
6           mize the risk of occupational exposure to bloodborne  
7           pathogens due to percutaneous injuries from con-  
8           taminated sharps. Comments were provided by  
9           health care facilities, groups representing healthcare  
10          workers, researchers, educational institutions, pro-  
11          fessional and industry associations, and manufactur-  
12          ers of medical devices.

13          (7) Numerous studies have demonstrated that  
14          the use of safer medical devices, such as needleless  
15          systems and sharps with engineered sharps injury  
16          protections, when they are part of an overall  
17          bloodborne pathogens risk-reduction program, can be  
18          extremely effective in reducing accidental sharps in-  
19          juries.

20          (8) In March 2000, the Centers for Disease  
21          Control and Prevention estimated that, depending  
22          on the type of device used and the procedure in-  
23          volved, 62 to 88 percent of sharps injuries can po-  
24          tentially be prevented by the use of safer medical de-  
25          vices.



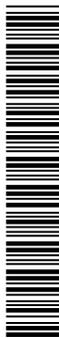
1           (9) The OSHA 200 Log, as it is currently  
2 maintained, does not sufficiently reflect injuries that  
3 may involve exposure to bloodborne pathogens in  
4 healthcare facilities. More than 98 percent of  
5 healthcare facilities responding to the RFI have  
6 adopted surveillance systems in addition to the  
7 OSHA 200 Log. Information gathered through these  
8 surveillance systems is commonly used for hazard  
9 identification and evaluation of program and device  
10 effectiveness.

11           (10) Training and education in the use of safer  
12 medical devices and safer work practices are signifi-  
13 cant elements in the prevention of percutaneous ex-  
14 posure incidents. Staff involvement in the device se-  
15 lection and evaluation process is also an important  
16 element to achieving a reduction in sharps injuries,  
17 particularly as new safer devices are introduced into  
18 the work setting.

19           (11) Modification of the bloodborne pathogens  
20 standard is appropriate to set forth in greater detail  
21 its requirement that employers identify, evaluate,  
22 and make use of effective safer medical devices.

23 **SEC. 3. BLOODBORNE PATHOGENS STANDARD.**

24           The bloodborne pathogens standard published at 29  
25 C.F.R. 1910.1030 shall be revised as follows:



1           (1) The definition of “Engineering Controls”  
2           (at 29 C.F.R. 1910.1030(b)) shall include as addi-  
3           tional examples of controls the following: “safer  
4           medical devices, such as sharps with engineered  
5           sharps injury protections and needleless systems”.

6           (2) The term “Sharps with Engineered Sharps  
7           Injury Protections” shall be added to the definitions  
8           (at 29 C.F.R. 1910.1030(b)) and defined as “a non-  
9           needle sharp or a needle device used for withdrawing  
10          body fluids, accessing a vein or artery, or admin-  
11          istering medications or other fluids, with a built-in  
12          safety feature or mechanism that effectively reduces  
13          the risk of an exposure incident”.

14          (3) The term “Needleless Systems” shall be  
15          added to the definitions (at 29 C.F.R.  
16          1910.1030(b)) and defined as “a device that does  
17          not use needles for (A) the collection of bodily fluids  
18          or withdrawal of body fluids after initial venous or  
19          arterial access is established, (B) the administration  
20          of medication or fluids, or (C) any other procedure  
21          involving the potential for occupational exposure to  
22          bloodborne pathogens due to percutaneous injuries  
23          from contaminated sharps”.

24          (4) In addition to the existing requirements  
25          concerning exposure control plans (29 C.F.R.



1 1910.1030(c)(1)(iv)), the review and update of such  
2 plans shall be required to also—

3 (A) “reflect changes in technology that  
4 eliminate or reduce exposure to bloodborne  
5 pathogens”; and

6 (B) “document consideration and imple-  
7 mentation of appropriate commercially available  
8 and effective safer medical devices designed to  
9 eliminate or minimize occupational exposure”.

10 (5) The following additional recordkeeping re-  
11 quirement shall be added to the bloodborne patho-  
12 gens standard at 29 C.F.R. 1910.1030(h): “The em-  
13 ployer shall establish and maintain a sharps injury  
14 log for the recording of percutaneous injuries from  
15 contaminated sharps. The information in the sharps  
16 injury log shall be recorded and maintained in such  
17 manner as to protect the confidentiality of the in-  
18 jured employee. The sharps injury log shall contain,  
19 at a minimum—

20 “(A) the type and brand of device involved  
21 in the incident,

22 “(B) the department or work area where  
23 the exposure incident occurred, and

24 “(C) an explanation of how the incident oc-  
25 curred.”.



1 The requirement for such sharps injury log shall not  
2 apply to any employer who is not required to main-  
3 tain a log of occupational injuries and illnesses  
4 under 29 C.F.R. 1904 and the sharps injury log  
5 shall be maintained for the period required by 29  
6 C.F.R. 1904.6.

7 (6) The following new section shall be added to  
8 the bloodborne pathogens standard: “An employer,  
9 who is required to establish an Exposure Control  
10 Plan shall solicit input from non-managerial employ-  
11 ees responsible for direct patient care who are poten-  
12 tially exposed to injuries from contaminated sharps  
13 in the identification, evaluation, and selection of ef-  
14 fective engineering and work practice controls and  
15 shall document the solicitation in the Exposure Con-  
16 trol Plan.”.

17 **SEC. 4. EFFECT OF MODIFICATIONS.**

18 The modifications under section 3 shall be in force  
19 until superseded in whole or in part by regulations promul-  
20 gated by the Secretary of Labor under section 6(b) of the  
21 Occupational Safety and Health Act of 1970 (29 U.S.C.  
22 655(b)) and shall be enforced in the same manner and  
23 to the same extent as any rule or regulation promulgated  
24 under section 6(b).



1 **SEC. 5. PROCEDURE AND EFFECTIVE DATE.**

2 (a) PROCEDURE.—The modifications of the  
3 bloodborne pathogens standard prescribed by section 3  
4 shall take effect without regard to the procedural require-  
5 ments applicable to regulations promulgated under section  
6 6(b) of the Occupational Safety and Health Act of 1970  
7 (29 U.S.C. 655(b)) or the procedural requirements of  
8 chapter 5 of title 5, United States Code.

9 (b) EFFECTIVE DATE.—The modifications to the  
10 bloodborne pathogens standard required by section 3  
11 shall—

12 (1) within 6 months of the date of enactment  
13 of this Act, be made and published in the Federal  
14 Register by the Secretary of Labor acting through  
15 the Occupational Safety and Health Administration;  
16 and

17 (2) at the end of 90 days after such publication,  
18 take effect.

